

### **REMARKS/ARGUMENTS**

In this Amendment, claims 45, 96, 99, 151 and 152 are currently amended. Claims 1-44, 56-76, 79, 82-86, 94, 95, 97, 98, 106-136, 138, 153-155, 158 and 159 are canceled without prejudice or disclaimer. Claims 46-55, 77, 78, 80, 81, 87-93, 100-105, 137, 139-150, 156, 157 and 160 were previously presented. Claims 161-168 have been newly added. Applicants retain the right to submit any or all of the claims that have been canceled without prejudice or disclaimer herein in a timely-filed continuing application.

No new matter has been introduced into the application by virtue of the amended and new claims. The amended and new claims are supported by the specification as filed. More specifically, claim 45, 96 and 99 have been amended to correct clerical oversights in the claim language. Support for the recitation of "4% or less" in amended claims 151 and 152 is found in the instant specification, *inter alia*, on page 26, in the formulations shown in Table IV. Formula 4.1 in Table IV contains no diluent and is an efficacious formulation, as disclosed on page 27, paragraph 1, of the instant specification. In addition, Formula 4.3 in Table IV contains 3% of the diluent. Further, as presented in Table II on page 23 of the instant specification, Formulation Number 2.15 contains 2% of the diluent Miglycol-810 (M810).

Support for new claims 161 and 165 is found in the instant specification, *inter alia*, on page 9, last paragraph, to page 10, first paragraph. Support for new claims 162 and 166 is found in the instant specification, *inter alia*, on page 10, first paragraph. Support for new claims 163, 164, 167 and 168 is found in the instant specification, *inter alia*, on page 10, second paragraph.

Accordingly, claims 45-55, 77, 78, 80, 81, 87-93, 96, 99-105, 137, 139-152, 156, 157 and 160-168 are currently pending in the application.

Applicants additionally acknowledge that claims 45-55, 77, 78, 80, 81, 87-93, 96, 99-105, 137, 139-150 and 160 have been formally allowed by the Examiner, as set forth on page 3 of the 04/08/2005 Office Action.

**The claims fulfill the requirements of 35 U.S.C. §103(a)**

Claims 56-61, 63-67, 69-76, 106-122, 125, 128-135 and 153-159 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over EPA 770387 ("EPA '387") in view of U.S. Patent No. 5,880,123 to T. Harrison and U.S. Patent No. 3,885,027 to Shaw et al.

Without acquiescing to the propriety of this rejection, Applicants respectfully submit that the rejection is mooted in view of the cancellation of claims 56-61, 63-67, 69-76, 106-122, 125, 128-135, 153-155, 158 and 159 without prejudice or disclaimer.

Applicants respectfully point out that claims 156 and 157, which the Examiner listed as allegedly being unpatentable under 35 U.S.C. §103(a), depend from claims 151 and 152, respectively, which were not included among the claims rejected under 35 U.S.C. §103(a). Thus, it is submitted that claims 156 and 157 should not have been included among the claims listed in the 35 U.S.C. §103(a) rejection.

In view of the foregoing, it is respectfully requested that the rejection under 35 U.S.C. §103(a) be withdrawn.

**The claims fulfill the requirements of 35 U.S.C. §112, second paragraph**

Claims 151-159 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. According to the Examiner, because claims 151(b), 152(b) and 153(b) recite "up to", which includes zero, it is unclear as to whether 0% diluent is included in these claims.

Applicants submit that the rejection of claims 153-155, 158 and 159 is moot in view of the cancellation of these claims without prejudice or disclaimer.

With regard to claims 151 and 152 and dependent claims 156 and 157, it is respectfully submitted that one having skill in the pertinent art would understand the metes and bounds of claims 151 and 152, as presently amended, in view of the disclosure of the as-filed specification. An amount of 4% or less of diluent is clearly supported by the disclosure of the instant specification, for example, on page 26, Table IV, in which Formula 4.1 contains no (i.e., 0%)

cholesteryl oleate as diluent, and Formula 4.3 contains 3% cholesteryl oleate as diluent. Further, as presented in Table II on page 23 of the instant specification, Formulation Number 2.15 contains 2% of the diluent Miglycol-810 (M810). Each of the foregoing formulations supports and exemplifies a diluent in an amount of 4% or less as recited in presently amended claims 151 and 152. Claim 156, which depends from claim 151 and encompasses the limitations of claim 151, is definite and satisfies §112, second paragraph. Similarly, claim 156, which depends from claim 152 and encompasses the limitations of claim 152, is also definite and satisfies §112, second paragraph.

Accordingly, reconsideration and withdrawal of the §112, second paragraph, rejection are respectfully requested for claims 151 and 152, as well as for their respective dependent claims 156 and 157, which should also be considered to be free of the cited art.

Applicants: Awadhesh K. Mishra, *et al.*  
Serial No.: 09/376,487  
Filed: August 18, 1999  
Page -15-

Docket No.: 28069-504  
(Formerly: 402090/SkyePharma)

### CONCLUSION

Applicants respectfully submit that this application is now in condition for allowance.  
An action progressing this application to issue is courteously urged.

Should any additional fees be deemed to be properly assessable in this application for the timely consideration of this amendment and response, or during the pendency of this application, the Commissioner is hereby authorized to charge any such additional fee(s), or to credit any overpayment, to Deposit Account No. **50-0311**, Reference No. **28069-504**, Customer No. **34537**.

If the Examiner is of the opinion that further discussion of the application would be helpful, the Examiner is hereby respectfully requested to telephone the undersigned at (212) 692-6742 and is assured of full cooperation in an effort to advance the prosecution of the instant application and claims to allowance.

Respectfully submitted,

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY  
AND POPEO, P.C.

Date: July 7, 2005

By: Leslie A. Serunian  
Leslie A. Serunian  
Registration No. 35,353

Correspondence Address:

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY  
AND POPEO, P.C.  
The Chrysler Building, 24<sup>th</sup> Floor  
666 Third Avenue  
New York, New York 10017  
Telephone: (212) 935-3000  
Facsimile: (212) 983-3115  
Direct Tel.: (212) 692-6742

Express Mail Label No.: EV 591029036US